

**REMARKS**

Claims 1-13, 15-18, 20-45 and 48-51 are pending in the present application. Claim 1 is an independent claim and has been amended herein. Claims 1, 3, 15-18, and 48-51 also have been amended. Claims 14 and 19 have been canceled. Claims 46 and 47, which were withdrawn by the Examiner as drawn to a non-elected invention, also have been canceled.

Support for the amendment to claim 1 can be found throughout the specification including, for example, at page 10, lines 3 to 15 and page 11, lines 22-23. Claim 3 has been amended to correct a minor grammatical error and claims 15-18 and 48-51 have been amended to change the claim from which they each depend.

Entry of the amendment is requested under 37 C.F.R. § 1.116 because the amendment: a) places the application in condition for allowance for the reasons discussed herein; b) does not present any additional claims without canceling the corresponding number of final rejected claims; and/or c) places the application in better form for an appeal, if an appeal is necessary. Entry of the amendment is thus respectfully requested.

Claims 14, 19, 46, and 47 have been cancelled herein to expedite prosecution by placing the application in condition for allowance but without waiver of or prejudice to the right to seek allowance of any claim as previously presented or any other claim that may be supported by the disclosure.

In view of the following remarks, favorable reconsideration and allowance of the present application is respectfully requested.

**I. Allowable Subject Matter**

Applicants acknowledge and appreciate the Examiner's indication that claims 19 and 48-51 are objected to as being dependent upon a rejected base claim, but

would be allowable is rewritten in independent form including all of the limitations of the base claim and any intervening claims. [Office Action p. 9].

## **II. Objections**

Applicants acknowledge and appreciate the Examiner's withdrawal of the objection to the specification for improper citation of trademarks and withdrawal of the objection to claim 3 for minor spelling informalities. [Office Action p. 2].

## **III. Claim Rejections**

### **A. Claim Rejections – 35 U.S.C. §112**

#### **1. Claims 1-45.**

Applicants acknowledge and appreciate the Examiner's withdrawal of the rejection of claims 1-45 under 35 U.S.C. §112, second paragraph as indefinite. [Office Action p. 2].

#### **2. Claim 17.**

Applicants acknowledge and appreciate the Examiner's withdrawal of the rejection of claim 17 under 35 U.S.C. §112, second paragraph as indefinite. [Office Action p. 2-3].

#### **3. Claim 19.**

Applicants acknowledge and appreciate the Examiner's withdrawal of the rejection of claim 19 under 35 U.S.C. §112, second paragraph as indefinite. [Office Action p. 3].

**A. Claim Rejections – 35 U.S.C. §102**

1. Claims 1, 3, 4, 6, 7, 10, 11, 14-17, 20, 22-25, 28, 35, and 36 & Ralls et al.

Applicants acknowledge and appreciate the Examiner's withdrawal of the rejection of claims 1, 3, 4, 6, 7, 10, 11, 14-17, 20, 22-25, 28, 35, and 36 as anticipated by Ralls et al. (U.S. 5,741,659). [Office Action pp. 3, 5]

2. Claims 1-4, 6-7, 10-13, 16-17, 20, 22-28, 35-36 and 40-45 & Tuompo et al.

The Examiner has rejected claims 1-4, 6-7, 10-13, 16-17, 20, 22-28, 35-36 and 40-45 under 35 U.S.C. §102(b) as being anticipated by Tuompo et al. (U.S. Patent No. 5,714,343)(herein "Tuompo '343").

As amended, claim 1 recites "wherein the at least one substrate produces the detectable moiety by being cleaved by an enzyme that is characteristic for the contaminants, and wherein the detectable moiety is detectable in an amount of at the most 100 picomoles." Applicants respectfully submit that Tuompo '343 fails to teach at least those features of claim 1. Indeed, the Examiner indicated in the Office Action that dependent claim 19, which recited "wherein the detectable moiety is detectable in an amount of at the most 100 picomoles," was allowable over the art of record, including Tuompo '343. [Office Action p. 9].

For at least these reasons, Tuompo '343 does not anticipate claim 1. Because claims 2-4, 6-7, 10-13, 16-17, 20, 22-28, 35-36 and 40-45 each depends, directly or indirectly, from claim 1, Tuompo '343 does not anticipate any of those claims for at least the same reasons that Tuompo '343 does not anticipate claim 1. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

3. Claims 1, 3-4, 6-7, 10-11, 14-15, 17, 20, 22-25, 27-28, 31-33 and 35-36 & Laine et al.

The Examiner has rejected claims 1, 3-4, 6-7, 10-11, 14-15, 17, 20, 22-25, 27-28, 31-33 and 35-36 under 35 U.S.C. §102(b) as being anticipated by Laine et al. (U.S. Patent No. 6,090,573)(herein “Laine ‘573”).

Claim 1, as amended, recites “wherein the at least one substrate produces the detectable moiety by being cleaved by an enzyme that is characteristic for the contaminants, and wherein the detectable moiety is detectable in an amount of at the most 100 picomoles.” Applicants respectfully submit that Laine ‘573 fails to teach at least those features of claim 1. Indeed, the Examiner indicated in the Office Action that dependent claim 19, which recited “wherein the detectable moiety is detectable in an amount of at the most 100 picomoles,” was allowable over the art of record, including Laine ‘573. [Office Action p. 9].

For at least these reasons, Laine ‘573 does not anticipate claim 1. Because claims 3-4, 6-7, 10-11, 14-15, 17, 20, 22-25, 27-28, 31-33 and 35-36 each depends, directly or indirectly, from claim 1, Laine ‘573 does not anticipate any of those claims for at least the same reasons that Laine ‘573 does not anticipate claim 1. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

**B. Claim Rejections – 35 U.S.C. §103.**

1. Claims 1-7, 10-13, 16-17, 20, 22-30, 35-36 and 40-45 & Tuompo et al.

The Examiner has rejected claims 1-7, 10-13, 16-17, 20, 22-30, 35-36 and 40-45 under 35 U.S.C. §103(a) as being unpatentable over Tuompo ‘343.

As discussed above, claim 1 recites “wherein the at least one substrate produces the detectable moiety by being cleaved by an enzyme that is characteristic for the contaminants, and wherein the detectable moiety is detectable in an amount of at the most 100 picomoles.” Applicants respectfully submit that nothing in Tuompo

'343 teaches or suggests at least those features of claim 1. Indeed, the Examiner indicated that dependent claim 19, which recited "wherein the detectable moiety is detectable in an amount of at the most 100 picomoles," was allowable over the art of record, including Tuompo '343. [Office Action p. 9].

For at least this reason claim 1 is not rendered obvious by Tuompo '343. Because claims 2-7, 10-13, 16-17, 20, 22-30, 35-36 and 40-45 each depends, directly or indirectly, from claim 1, Tuompo '343 does not render any of those claims obvious for at least the same reasons that Tuompo '343 does not render claim 1 obvious. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

2. Claims 1-7, 10-13, 16-18, 20, 22-30, 35-38 and 40-45 & Tuompo et al. in view of Koumura et al.

The Examiner has rejected claims 1-7, 10-13, 16-18, 20, 22-30, 35-38 and 40-45 under 35 U.S.C. §103(a) as being unpatentable over Tuompo et al. (U.S. Patent No. 5,714,343) in view of Koumura et al. (U.S. Patent No. 4,591,554).

As discussed above, Tuompo '343 fails to teach or suggest features recited in claim 1 and therefore does not render claim obvious. Applicants respectfully submit that nothing in Koumura '554 cures the deficiencies of Tuompo '343. For example, Applicants submit that nothing in Koumura '554 teaches or suggests a detectable moiety that is detectable in an amount of at the most 100 picomoles. Indeed, the Examiner indicated that dependent claim 19, which recited "wherein the detectable moiety is detectable in an amount of at the most 100 picomoles," was allowable over the art of record, including Tuompo '343 and Koumura '554. [Office Action p. 9].

For at least these reasons, claim 1 is not rendered obvious by Tuompo '343 in view of Koumura '554. Because claims 2-7, 10-13, 16-18, 20, 22-30, 35-38 and 40-45 each depends, directly or indirectly from claim 1, Tuompo '343 in view of Koumura

'554 does not render any of those claims obvious for at least the same reasons that Tuompo '343 in view of Koumura '554 does not render claim 1 obvious. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

3. Claims 1, 3-4, 6-11, 14-15, 17, 20-25, 27-28, 31-36 and 39 & Laine et al.

The Examiner has rejected claims 1, 3-4, 6-11, 14-15, 17, 20-25, 27-28, 31-36 and 39 under 35 U.S.C. §103(a) as being unpatentable over Laine et al. (U.S. Patent No. 6,090,573).

As discussed above claim 1 recites "wherein the at least one substrate produces the detectable moiety by being cleaved by an enzyme that is characteristic for the contaminants, and wherein the detectable moiety is detectable in an amount of at the most 100 picomoles," and Laine '573 fails to teach or suggest at least those features of claim 1. Indeed, the Examiner indicated in the Office Action that dependent claim 19 which recites "wherein the detectable moiety is detectable in an amount of at the most 100 picomoles," was allowable over the art of record, including Laine '573. [Office Action p. 9].

For at least these reasons, claim 1 is not rendered obvious by Laine '573. Because claims 3-4, 6-11, 14-15, 17, 20-25, 27-28, 31-36 and 39 each depends, directly or indirectly, from claim 1, Laine '573 does not render any of those claims obvious for at least the same reasons that Laine '573 does not render claim 1 obvious. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

**CONCLUSION**

Accordingly, in view of the above amendments and remarks, reconsideration of the objections and rejections and allowance of each of claims 1-13, 15-18, 20-45 and

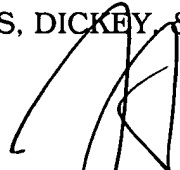
48-51 in connection with the present application is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Bradford Paul Schmidt at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. §1.17; particularly, extension of time fees.

Respectfully submitted,

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